

REMARKS

Applicants will address each of the Examiner's rejections in the order in which they appear in the Office Action.

Claim Rejections - 35 USC §102

Nita

In the Office Action, the Examiner rejects Claim 29 under 35 USC §102(b) as being anticipated by Nita (US 5,267,954). This rejection is respectfully traversed.

While Applicants traverse this rejection, in order to advance the prosecution of this application, Applicants have amended Claim 29. Independent Claim 29 of the present application is directed to a catheter for use in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element movable in the catheter by means of pressurized fluid. The amended claim further recites that the treating element comprises a hollow cylinder encapsulating a radioactive material. As explained below, Nita does not disclose or suggest such a catheter nor such a treating element.

In contrast to the catheter of Claim 29, Nita is directed to an ultra-sound catheter which has an ultrasound transmission member or wire "extending longitudinally therethrough" (see Abstract in Nita). As explained in Col. 5, lns. 17-23 of Nita, the ultrasound transmission member or wave guide (24) extends longitudinally through the lumen of the catheter body to transmit ultrasound energy from an ultrasound transducer connected to the proximal end of the catheter to the distal end thereof. There appears to be no disclosure or suggestion of a treating element which has radioactive material, or a treating element comprising a hollow cylinder encapsulating the radioactive material, or a

catheter in which the treating element is movable by means of pressurized fluid, as in independent Claim 29.

Accordingly, for at least the above-stated reasons, independent Claim 29 and the claims dependent thereon are clearly patentable over the cited reference. Therefore, it is respectfully requested that this rejection be withdrawn.

Weaver

The Examiner also rejects Claims 29-32 under 35 USC §102(e) as being anticipated by Weaver et al. (US 5,843,028). This rejection is also respectfully traversed.

In particular, the Examiner alleges that Weaver discloses a first tube having a lumen closed at its distal end and sized to receive the treating element, a second tube in parallel relation to the first tube and having a lumen open at its distal end and sized to receive a guidewire, and a third tube for receiving the first and second tubes and having a fluid return lumen in fluid communication with the lumen of the first elongated tube. Applicants disagree with this characterization of Weaver.

Weaver is directed to a catheter for advancement into a body passage into the gastrointestinal system (see Abstract). While Weaver does disclose a lumen for receiving a guidewire, it does not disclose a first tube having a lumen closed to outside the catheter at its distal end for receiving a treating element, as required in Claims 29-32. Instead, Weaver discloses lumens which have an exit port in the distal tip of the catheter for injecting contrast medium or dye into the gastrointestinal system (see e.g. col. 3, lns. 21-25, 42-45; col. 4, lns. 55-65; col. 6, lns. 38-49; col. 8, lns. 8-11 (“[i]n all embodiments, lumens 32 and 34 exit through ports in the distal tip...”); col. 9, lns. 53-56, etc in Weaver). Hence, unlike the claimed invention, these lumens are not closed at the distal end but must have an opening for injecting the contrast medium into the gastrointestinal system.

In order to make this distinction clearer and to advance the prosecution of this application, Applicants have amended independent Claims 29 and 30 to recite that the catheter has a first lumen closed to outside the catheter at its distal end.

Further, there is no disclosure or suggestion in Weaver of a third elongated tube with a return lumen in fluid communication with the first elongated tube. Applicants can find nothing in the cited drawings from the reference or the disclosure in the reference showing a fluid communication between the lumens, and in fact, there is no reason for such fluid communication in Weaver. Instead, Weaver states that all the embodiments in the reference have a lumen with an exit port (to outside the catheter) at the distal tip for injection of contrast medium (see e.g. col. 8, lns. 6-11). Each of these lumens is intended to deliver contrast medium from the lumen through the distal tip (via the port on the distal end) of the catheter to the gastrointestinal system of the patient. Hence, it would make absolutely no sense to have a return fluid lumen or a mechanism for the contrast medium lumen to be in fluid communication with another lumen in the catheter. Such a return fluid lumen would only result in contrast medium not being injected into the gastrointestinal system and being of no value. This would defeat the whole purpose of the Weaver device.

Accordingly, for at least the above-stated reasons, Weaver fails to disclose or suggest the claimed invention, and the claims of the present application are clearly patentable over the cited reference. Therefore, it is respectfully requested that this rejection be withdrawn.

Harrison

The Examiner also rejects Claims 29-32 under 35 USC §102(e) as being unpatentable over Harrison et al. (US 5,554,119). This rejection is also respectfully traversed.

In particular, the Examiner alleges that Harrison discloses a catheter having a first tube (172) having a lumen partially closed at its distal end and sized to receive the treating element, a second tube (32) in parallel relation to the first tube and having a lumen open at its distal end and sized to receive a guidewire; and a third tube (164) for receiving the first and second tubes and having a fluid return lumen in fluid communication with the lumen of the first elongated tube.

Applicants respectfully disagree with this characterization of the reference by the Examiner. For example, in contrast to the Examiner's statement, Harrison discloses the following three lumens: (1) an inflation lumen 36 formed of three sections (Col. 9, Ins. 12-16), (2) a lumen 34 for a guidewire and (3) a drug delivery lumen 38 (Col. 9, Ins. 10-7). Contrary to the Examiner's characterization, Harrison describes 172 as "the bond of 172 of the middle inflation lumen tubing 164 to the proximal inflation lumen 166" (which is all part of the same inflation lumen 36). Hence, 172 is not a lumen or a tube, as required in the claims of the present application. Further, 172 is also not sized to slidingly receive a treating element, as recited in claims of the present application. Also, contrary to the Examiner's characterization, 164 is a middle inflation lumen section of lumen 36, not a fluid return lumen as in the claimed invention. Further, while Harrison discloses a drug delivery lumen 38, there is no disclosure or suggestion of this tube having an opening in fluid communication with the alleged third tube, as recited in the claims of the present application.

In a related application, USSN 09/468,496, the Examiner contends that Applicants are making arguments directed to the functional language of the first and third lumens and not structure. Further, the Examiner argues that "the third lumen [of Harrison] encompasses the first and second lumen[s], and therefore would be able to perform the function of acting as a return lumen, since there is a proximal port as shown in figure[s] 15 and 16."

Applicants respectfully disagree. First, as shown above, Applicants are pointing out specific structural features of the claimed invention that are not disclosed in Harrison.

Further, an alleged proximal port in Harrison cannot convert 164 into a return lumen, as such term is defined in the present application. In particular, the present invention is directed to a catheter for delivering treating elements to a selected site in the body. As explained in the present application and as claimed, those treating elements include radioactive material. With such radioactive material, it is desirable to have the radioactive material at the selected area only, for treatment of that area, only for a desired amount of time, without exposing the other tissue to such treatment or radioactivity. This is accomplished in the present invention by having a lumen in the first elongated tube for receiving the treating element wherein the treating element is moved to the distal end of the lumen of the first elongated tube and the treatment area very quickly through the use of pressure fluid. Once the treatment is finished, the treating elements are quickly returned to the proximal end of the catheter through the fluid return lumen of the third elongated tube. This is accomplished by having the fluid return lumen in fluid communication with the lumen of the first elongated tube at the distal end of the first elongated tube. As explained above and as recited in independent Claims 29 and 30, these lumens are in fluid communication via an opening in the lumen of the first elongated tube at the distal end of the first elongated tube. If the two lumens are not in fluid communication at the distal end, as required in the claimed invention, then the catheter will not work for its intended purpose and would leave the radioactive treating elements in the body much longer than desirable.¹

¹ This is not a concern in Harrison as the reference is directed to a catheter for delivery and release of a drug at an area to be treated. It is not necessary with the Harrison device to remove the drug from the body through the catheter.

The Examiner is contending that an alleged proximal port² in the Harrison device performs the function of return lumen. First, a proximal port fails to meet the claimed feature that the return fluid lumen and the lumen of the first elongated tube are in fluid communication at the distal end of the lumen of the first elongated tube. Further, Claims 29 and 30 now specifically recite that the fluid return lumen is in fluid communication with an opening in the lumen of the first elongated tube at the distal end of the first elongated tube. Clearly, Harrison does not disclose or suggest such an opening at the distal end, and the alleged proximal port would not read on such a feature.

Further, this alleged proximal port could not act as a fluid return lumen as claimed and taught in the present application, for at least the reasons explained above.

Hence, Harrison does not disclose or suggest the claimed invention. Therefore, the claims are patentable thereover, and it is respectfully requested that this rejection be withdrawn.

Double Patenting

US 5,899,882

The Examiner also rejects Claims 29-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, 17, 19, 20, 22, 35 of US 5,899,882. This rejection is respectfully traversed.

Applicants respectfully submit that the claims of the present application are not claiming the same thing as claimed in the ‘882 patent.³ Initially, Applicants note that the Examiner has already taken the position that the feature of independent Claims 29 and 30 of the present application, of

² It is not clear from the Office Action as to where this alleged proximal port is in Figs. 15 and 16.

³ The ‘882 patent was filed as a continuation-in-part of the great-grandfather of the present application, which was filed prior to the ‘882 patent.

wherein the third elongated tube is closed at the distal end, is independent or distinct (see USSN 09/468,496 as explained below).

Other features recited in the claims of the present application, but not in the claims of the '882 patent, include, but are not limited to, the following:

- (a) treating element comprising a hollow cylinder encapsulating a radioactive material;
- and
- (b) first elongated tube having a lumen closed to outside said catheter at its distal end.

Features recited in claims 11, 12, 17, 19, 20, 22 and 35 of the '882 patent, but not recited in the claims of the present application, include, but are not limited to, the following:

- (a) communication between the lumens effected through a reinforcing connector;
- (b) the lumen for the guidewire having at least one aperture between the outer wall of the tube and the third lumen to facilitate perfusion of fluids past the catheter;
- (c) the catheter further comprising a radiopaque marker at the distal end;
- (d) tube having an outside diameter sufficiently large with respect to the intraluminal passageway to center the treatment elements within the passageway;
- (e) at least one balloon at said distal end for centering distal end of the catheter; and
- (f) an extending recess along the outer wall of said tube to permit perfusion of fluids past the catheter.

Hence, the claims of the present application and the claims of the '882 patent are clearly different. Accordingly, it is respectfully requested that this rejection be withdrawn.

USSN 09/468,496

The Examiner also objects to Claims 29-32 as being in conflict with Claims 29-35, 37, 42-44, 47-49 of USSN 09/468,496. This rejection is also respectfully traversed.

Claims 29, 30, and 31 of the present application were originally filed in the '496 application as Claims 41, 45, 46, respectively (see Amendment C filed September 11, 2003 in the '496 application). The Examiner of the '496 application, however, stated that "Newly submitted claims 41, 45 and 46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to a non-elected species... Accordingly, claims 41, 45 and 46 are withdrawn from consideration as being directed to a non-elected invention." (see Office Action of December 2, 2003). As a result of that holding, Applicants filed the present application.

As the Examiner of the '496 application is the same as the Examiner of the present application, it is respectfully submitted that this objection is erroneous, and it is respectfully requested that it now be withdrawn.

Conclusion

Therefore, for at least the above-stated reasons, the present application is in an allowable condition and should be allowed.

If any further fee is due for this amendment, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

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